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Original Research Article

A randomised controlled study for the comparison of functional outcome of femoral tunnel fixation devices, aperture fixation by screw vs suspensory fixation by endo-button in arthroscopic anterior cruciate ligament reconstruction

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ABSTRACT

Purpose: The goal of this study was to compare suspensory and aperture fixation methods for restoring soft tissue allografts in the anterior cruciate ligament (ACL).

Materials and Methods: 30 patients were chosen and randomly allocated to one of two experimental groups, suspensory fixation or aperture fixation, following the completion of a prospective analysis, permission from the institutional review board, and patient agreement. All of the patients underwent ACL reconstruction surgery using soft tissue allografts made of hamstring tendon. The procedures were either (1) femoral and tibial fixation with a femoral cannulated interference screw and a tibial cannulated interference screw (aperture) or (2) femoral cortical buttons (suspensory) and a tibial cannulated interference screw. The subjective anterior drawer test analysis and changes in the International Knee Documentation Committee knee examination rating were employed as end measures.

Results: All of the patients who had received treatment (100%) had successfully completed a clinical assessment at the 1-month, 4-month, 8-month, and 12-month follow-ups. Out of the 30 patients who were included, 15 (50%) underwent suspensory fixation treatment and the other 15 (50%) underwent aperture fixation treatment. The primary outcome measure—AP stability at 25 degrees of knee flexion—did not differ across groups at a 12-month follow-up. Also, at the 1-month and 4-month evaluations, secondary data revealed a statistically significant difference between the groups.

Conclusions: Our data showed no meaningful differences in knee AP stability or other outcomes between ACL allograft reconstruction using aperture fixation and ACL allograft reconstruction utilising suspensory fixation at the 12-month mark, while aperture fixation performed better at the first and fourth months. One of our main outcome measures was the grading of knee anteroposterior (AP) stability (clinical judgments).

Level of Evidence: Level II, lesser-quality randomised controlled trial with a follow-up of 1 year.

1. Introduction

By joining the femur and tibia, the anterior cruciate ligament (ACL) stabilises the knee joint. The ACL prevents rotation of the tibia with respect to the femur and anterior translation in the sagittal plane. The anterior cruciate ligament (ACL) connects the anterior aspect of the tibial plateau to the posterior aspect of the intercondylar notch on the femur. One of the most frequent knee ailments among sportsmen is ACL damage.[1] They most frequently affect those who take part in pivoting sports (e.g.football, basketball, netball, soccer, gymnastics, downhill skiing). One of the many aspects of primary anterior cruciate ligament restoration (ACL-R) with hamstring tendon (HS) autografts that can

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affect clinical outcomes is graft fixation. Graft fixation is frequently considered as the weakest link in the initial postoperative period.[2] Suspensory graft fixation versus aperture graft fixation is recognised as the second-most important factor in assessing the integrity and efficacy of ACL-R.[3]

The type of graft fixation chosen is influenced by a number of factors, including surgeon choice and training, cost, ease of use, and clinical experience.[4] The ideal ACL-R attachment technique must meet the requirements of being robust, rigid, and non-slip. Moreover, it has been demonstrated that the technique for graft attachment can influence the risk of revision following ACL-R.[5]

According to studies, suspension fixation techniques have stronger pull-out capabilities than multiple aperture fixation techniques.[6,7]

While some studies have found greater knee stability and reduced graft-tunnel motion under anterior tibial loading, other studies have found potential risks associated with aperture techniques of fixation, including the possibility of tunnel blow-out and the screw's potential to affect tendon-to-bone healing.[8]

There isn't a definite agreement on the ideal technique for graft fixation when it comes to suspensory fixation versus soft-tissue graft-aperture fixation.[9] There haven't been any prospective studies comparing graft fixation for HS despite multiple randomised control trials comparing graft fixation of the quadriceps tendon (QT) and bone-patellar tendon-bone (BPTB).

The majority of the literature on graft fixation has examined retrospective data and small patient cohorts, with no specific examination for the most effective graft attachment method.[10]

This randomised clinical trial compared the results and side effects of primary ACL reconstruction using hamstring tendon autografts in various graft fixation techniques.

It was predicted that aperture (i.e., intratunnel) fixation, as opposed to suspensory (i.e., extra-tunnel) fixation, would be associated with better clinical outcomes in the early postoperative phases, such as better patient-reported outcome measures.

2. Materials and Methods

We conducted a randomised controlled trial in which patients were assigned to one of two studies following prospective analysis, institutional review board approval, and patient agreement. Every patient had soft-tissue hamstring allograft ACL restoration using either[1] femoral and tibial joint-line fixation with screws (aperture) or[2] femoral side endobutton and tibial cortical interference screw (suspensory).

2.1. Inclusion and exclusion criteria

Patients between the ages of 18 and 45 with an ACL deficiency knee who chose to have allograft tissue used in an ACL reconstruction procedure met the inclusion criteria. At the surgeon's discretion, patients with related isolated ACL injuries were included and managed during ACL restoration. Patients with previous ACL reconstruction surgery or meniscus tears at the time of the research procedure were excluded, as were those with tears of the medial collateral ligament, posterior cruciate ligament, lateral collateral ligament, posteromedial corner, or postero-lateral corner of the knee (intra-operative exclusion criterion).

Patients who were expecting or couldn't read or understand English were also disqualified. Measurements of Results The International Knee Documentation Committee (IKDC) knee form was used to preoperatively collect patient demographic information, such as age and sex, and to document surgical observations of meniscal and cartilage disease. Following surgery, the knee IKDC score at a 1, 4, 8, or 12-month follow-up was the main outcome indicator. Joint laxity was assessed using the anterior drawer displacement knee evaluation and knee examination scores at 1, 4, 8, and 12 months as secondary end measures. Adverse surgical outcomes were also noted.

2.2. Surgical technique

Under spinal anaesthesia, all patients had ACL allograft reconstruction, and hamstring tendon grafts were whip-stitched with ethibond 5.0 suture. Typical saline was used to soak the grafts. A spade-tip Beath pin and low-profile reamers were used to generate femoral sockets using the anteromedial portal approach, and a tibial jig was used to create tibial sockets (Arthrex).

A titanium femoral interference screw and tibial interference screw (Arthrex) with diameters 1 mm smaller than the femoral and tibial socket diameters were used for aperture fixation.

A femoral endobutton with a predetermined loop length (Arthrex) and tibial sutures tied over a titanium cortical button with an 8–11 mm diameter were used for suspension fixation (Arthrex). The grafts were manually tensioned during fixation using a tibial-side tensioning technique. Postoperative ACL rehabilitation included an immediate focus on full extension, straight-ahead running at 3 months, and pivoting at 6 months.

2.3. Outcome measures

Data were collected and recorded at 2 weeks, 1 month, 4 months, 8 months and 12 months.

Statistical methods sample size analysis showed that a sample of 15 patients per group was required to detect a clinically relevant between the 2 groups.

Data were entered into a computerised software SPSS and also manually verified. Means and standard deviations are reported. A statistical test was used to compare IKDC knee examination scores and analyses were performed in consultation with a biostatistician.

Results from 15 patients were enrolled in each group. After enrolment, the study group suspensory fixation included 12 men and 3 women, with a mean age of 31.73±2.55 years. The control group aperture fixation ultimately included 13 men and 2 women, with a mean age of 32.4±3.09 years. There were no differences between groups regarding age (P - 0.366), and sex (P - 0.409) (Table 1).

The distribution of the injury side was as described in (Table 2) and there was no statistical difference between both groups.

At 12 months, 15 surgically treated patients in the suspensory group and 15 surgically treated patients in the aperture group completed the final follow-up.

The outcome measure IKDC, anterior drawer displacement knee AP stability at 25 of knee flexion, showed no difference between groups.

Outcome measures showed a difference between groups at 1st and the 4th-month follow-up (Table 3). There were no complications or adverse events in either group.

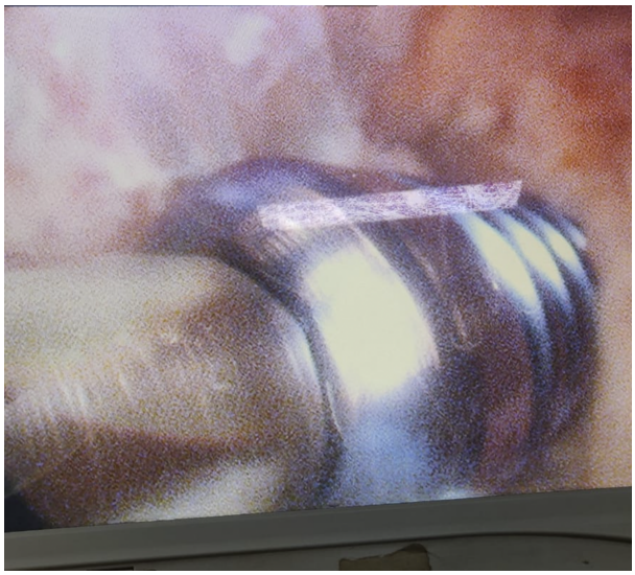

Fig. 1: Suspensory fixation

3. Discussion

As most of the patients in our study were between the ages of 31 and 35, the p-value was statistically insignificant (p 0.05) since the mean age of patients in the suspensory group was 31.733 years, while the mean age of patients in the aperture group was 32.4 years. These results are

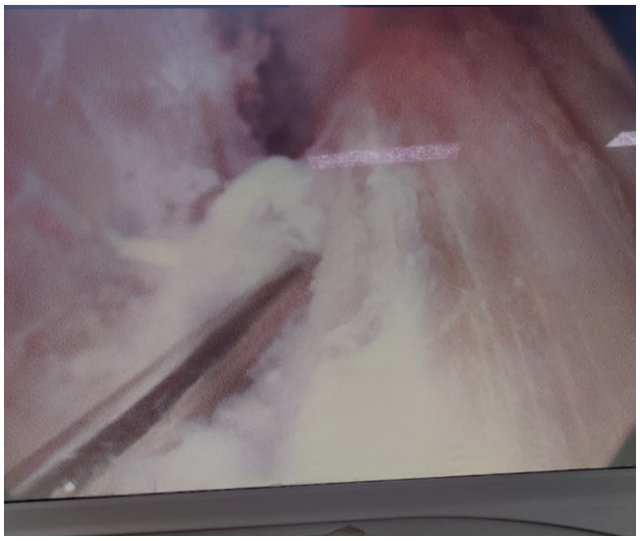

Fig. 2: Aperture fixation

consistent with earlier research.[11] 15 patients were eligible for the trial, with 9.99% of the suspensory patients being female and 39.96% of the aperture patients being male. The aperture group had 33.33% men and 16.15% women; since the p-value is greater than 0.05, both groups can be considered comparable. Our results agree with those of earlier research. The predominance of men may be due to their propensity for exerting themselves outside and in physically demanding activities.[12] The main finding of our study is no significant clinical difference for ACL allograft fixed with cortical suspensory button fixation versus aperture screw fixation at the 12^{th} months and a statistically significant difference at the 4th and 1st months in the aperture group. These findings have therapeutic significance for surgeons undertaking ACL reconstruction because the ACL-R technique has evolved, moving from aperture fixation to suspensory fixation, which has been characterised as a more straightforward and repeatable procedure. Both strategies have advantages in theory. In theory, if the elastic modulus of the graft is supposed to be constant along its length, fixation at the aperture results in a shorter overall length of the graft construct, increasing the stiffness of the knee by mitigating the "bungee cord" effect.[9] Biomechanical laboratory research has provided evidence in favour of this notion.[11] The "windscreen wiper" effect, in which suspensory fixation can allow the graft "to travel sagittally back and forth between the tunnel borders as the knee flexes and expands," is another potential benefit of fixing at the aperture.[13] Theoretically speaking, suspensory fixation is advantageous. It has been demonstrated in the anatomy lab that the ACL's tibial and femoral insertions cover a sizable surface area, or "footprint,",[14] which may be more closely replicated via suspensory fixation. Contrary to suspensory fixation, aperture fixation (using interference

Table 1: Distribution of age and sex

	Suspensory	Aperture	Statistics	P value
Age , Mean SD, yr	31.7333 ±2.557 (±8.06%	32.4 ±3.089 (±9.53%)	0.9106	0.3663
Sex, N	12 male 3 female	13 male 2 female	0.6818	0.409

Table 2: Distribution of patients according to the side of the operation

Injured site	Aperture fixation	Suspensory fixation	Chi square value	P value
Right	9 (29.97%)	8 (26.64%)	0.1357	0.71
Left	6 (19.98%)	7 (23.31%)		

Table 3: Distribution of patients according to IKDC

	Aperture	SD	Suspensory	SD	Statistics (T value)	P value
Preoperative	48.30	2.80	49.12	2.14	0.89	0.38
Postoperative						
1 month	66.27	4.66	61.22	3.59	3.32	0.0025
4 month	76.92	4.88	71.41	3.90	3.41	0.0020
8 month	83.55	1.85	83.28	1.89	0.38	0.69
12 month	92.56	1.86	92.28	1.90	0.38	0.70

screws at the joint line) compromises the footprint area since the screws themselves take up a large portion of the space, displacing graft collagen. Less of the footprint's anatomical structure is restored as a result. We are not aware of any published studies that would test this notion or provide clinical proof that reconstructing the anatomical footprint makes the knee more stable. The meta-analysis by Ilahi et al.[15] which likewise finds no clinical differences between intra-tunnel fixation and extra-tunnel fixation of soft-tissue ACL repair grafts, supports the main conclusion of our investigation. The fact that we found a difference in functional result between groups at 1 and 4 months, although the majority of earlier studies found none, is one conclusion of our study that is not supported by the literature. Although we are unable to provide an explanation for this disparity that is supported by data. It is also likely that disparities between our findings and those of earlier research were caused by additional, unexplained confounding factors because of the intricacy of ACL surgery, including fixation. In comparison to suspensory in our investigation, aperture fixation was reported to result in a mean IKDC knee examination rating of normal in 92.5% of patients at the end follow-up. Additionally, when our results and the previously released results of all-inside aperture fixation[12] are in agreement are in concordance with our results.

This conclusion seems significant because the transition of aperture 54eswa[16] to suspensory fixation is the trend in all-inside ACL repair, and it is comforting that the more widely used experimental technique (suspensory fixation) did not produce inferior results than the control technique (aperture fixation). This does not mean that suspensory fixation scores and aperture fixation scores were equal at the end of the study.

4. Limitations

Our study's primary drawback is its tiny patient sample size. Moreover, we did not include individuals who were older than 45. Gentamicin was administered to all grafts, however it is unknown whether this had any impact on the results. Suspensory fixation may be favourable for individuals with osteoporosis because of its greater pullout strength, even though osteoporosis was not evaluated. Osteoporosis is connected with ageing. Each patient chondral pathology differed, and due to the small sample size, no subgroup analysis was carried out. The sample size is modest, and it is conceivable that a bigger sample size would/may show less than 90% normal ratings, despite the fact that we report normal IKDC ratings in more than 90% of patients in the suspensory group.

5. Conclusions

After a 12-month follow-up, our findings reveal no appreciable differences in knee AP stability or other outcomes between ACL allograft surgery performed using aperture fixation versus ACL allograft reconstruction performed using suspensory fixation.

6. Source of Funding

None.

7. Conflict of Interest

None.

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